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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,152	04/25/2006	Frank I. Marcus	121873.00002US3	3679

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EXAMINER	
SCHAETZLE, KENNEDY	
ART UNIT	PAPER NUMBER
3766	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,152	MARCUS ET AL.	
	Examiner	Art Unit	
	Kennedy J. Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 20 is objected to because of the following informalities: the reference to the processing device comparing the hemodynamic parameter is vague since it is unclear what the hemodynamic parameter is being compared to. The examiner will assume it was the applicants' intent to compare hemodynamic parameters obtained from different lead locations. The examiner suggests first reciting that the means for determining a hemodynamic parameter based on SGC data obtains a first hemodynamic parameter from a first lead position and obtains a second hemodynamic parameter from a second different lead position, and then reciting that the processing device compares the first hemodynamic parameter to the second hemodynamic parameter and determines the optimal placement of leads responsive to said comparison. Appropriate correction is required.

2. Claims 2-9 and 12-19 are objected to because of the following informalities: active steps in the method must be set forth positively. For example, in claim 4, rather than reciting that the mapping is generated from the SCG data, one should rather refer to the active step of *generating* from the SCG data a ventricular contraction mapping in order to make clear that one is claiming the step of generating the map. Likewise with claims 5-9 and 15-19 a step of *determining* should be set forth (e.g., "…determining a pre-ejection period from a ventricular contraction mapping," etc.). Similarly, detecting and selecting steps should be recited in claims 2, 3, 12 and 13. Appropriate correction is required.

3. Claims 5-9 and 15-19 are objected to because of the following informalities: the reference to ventricular contraction mapping is vague as there have been no prior steps recited to determine such a mapping such that the various parameters recited can be determined therefrom. Either dependency of claims 5-9 and 15-19 should be based from claims 4 and 14 respectively, or the step of generating the contraction mapping should be set forth in each of claims 5-9 and 15-19. Appropriate correction is required.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,978,184. Although the conflicting claims are not identical, they are not patentably distinct from

each other because they are merely broader in scope than those of the '184 patent (the only substantive difference being the elimination of the term "electrophysiological" from the present claims). Once the applicant has received a patent for a species or a more specific embodiment, he is not entitled to a patent for the generic or broader invention (see *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)).

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed process is not tied to another statutory class (a particular machine or apparatus) and/or does not transform underlying subject matter (such as an article or materials) to a different state or thing (see *In re Bilski*, 545 F. 3d 943, 88 USPQ2d 1385 (Fed. Cir. 2008)). Mere field-of-use limitations or the recitation of a specific machine or particular transformation of a specific article in an insignificant step, such as data gathering or outputting, will generally not transform an unpatentable principle into a patentable process.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathis et al. (Pub. No. 2002/0169484) in view of Mouchawar et al..

Regarding claim 1, Mathis et al. disclose a resynchronization therapy method (see for example par. 0042), wherein data corresponding to heart motion is collected and compared to new stimulation patterns to ascertain whether the new pattern was effective in improving the hemodynamic condition of the heart (see for example pars. 0074-0077 and 0088-0090). While Mathis et al. do not explicitly suggest that seismocardiographic (SCG) data can be collected. Those of ordinary skill in the art, however, have recognized that SCG sensors can be used to obtain valuable information on the hemodynamic state of the heart and in particular wall movement. Mouchawar et al., for example, teach that cardiac wall displacement signals can be detected by seismic accelerometers and that the data produced by such sensors strongly correlates to the hemodynamic performance of the heart (see “Summary of the Invention”). By

using such data, Mouchawar et al. teach that one can better tailor pacing therapy to the individual under treatment. Those of ordinary skill in the art looking to accurately detect the hemodynamic state of the heart in order to effectively and judiciously apply cardiac stimulation such as suggested by both Mathis et al. and Mouchawar et al., would have therefore seen the obviousness of using SCG data to aid Mathis et al. in their quest to determine the optimal stimulation electrode set.

Regarding the collection of un-paced data, those of ordinary skill in the art would have recognized the need for a baseline reference from which to compare incoming data in order to judge the effectiveness of stimulation. Common sense dictates that when first examining a patient, the patient's natural cardiac state should be measured in order to understand the severity of the patient's problem before ascertaining the effect of any pacing therapy on the system –at least on a first iteration. To therefore provide at least one comparison between the patient's natural un-paced state and a first paced therapy in order to determine whether or not the paced therapy improved or worsened the patient's condition with respect to the intrinsic unaided state of the heart, would have been considered obvious by those of ordinary skill in the art.

Regarding claims directed to the various cardiac parameters, see par. 0062-0064. Clearly all of the parameters set forth in the current invention are well-known in the cardiac treatment arts and known to affect cardiac output. It would have been obvious to those of ordinary skill in the art that the particular cardiac parameter chosen to control and optimize the hemodynamic output would have been dependent upon the

particular heart condition and responsiveness of the individual under treatment and the prerogative of the physician under whose care the patient resides.

11. Claims 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim (Pat. No. 6,285,898) in view of Mouchawar et al. (Pat. No. 5,480,412).

Regarding claim 11, note col. 11, line 59- col. 12, line 5, col. 30, lines 28-63, etc.. While Ben-Haim teaches to determine a value of a hemodynamic parameter, he does not explicitly suggest that seismocardiographic (SCG) data can be used to determine the parameter. Those of ordinary skill in the art, however, have recognized that SCG sensors can be used to obtain valuable information on the hemodynamic state of the heart. Mouchawar et al., for example, teach that cardiac wall displacement signals such as discussed by Ben-Haim (see for example, col. 14, lines 15-26, etc.) can be detected by seismic accelerometers and that the data produced by such sensors strongly correlates to the hemodynamic performance of the heart (see "Summary of the Invention"). By using such data, Mouchawar et al. teach that one can better tailor pacing therapy to the individual under treatment. Those of ordinary skill in the art looking to accurately detect the hemodynamic state of the heart in order to effectively and judiciously apply cardiac stimulation such as suggested by both Ben-Haim and Mouchawar et al., would have therefore seen the obviousness of using SCG data to aid Ben-Haim in his quest to determine the optimal lead placement location. Similar comments apply to the rejection of claim 20.

Regarding claims 13-19, 22 and 23 see col. 9, lines 20-25, cols. 12, 13 and 17, col. 28, lines 40-57, etc., where various mapping schemes are discussed along with the

detection of ventricular contraction, ejection fraction, ventricular pressure, etc.. Although Ben-Haim does not appear to explicitly discuss determining the rate of contraction of the left ventricle, duration of systole, and the isovolumetric relaxation period, it is taught that a number of cardiac physiological variables can be optimized using the invention (see for example col. 28, lines 40-57). Clearly all of the parameters set forth in the current invention are well-known in the cardiac treatment arts and known to affect cardiac output. It would have been obvious to those of ordinary skill in the art that the particular cardiac parameter chosen to control and optimize the hemodynamic output would have been dependent upon the particular heart condition and responsiveness of the individual under treatment and the prerogative of the physician under whose care the patient resides.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy J. Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on M-F at 571 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766

KJS
February 20, 2009